

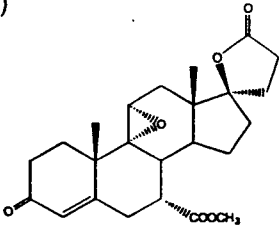

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-437/S-002

Chemistry Review(s)

CHEMIST'S REVIEW #1		1. ORGANIZATION HFD-110 DCRDP		2. NDA NUMBER 21-437	
3. NAME AND ADDRESS OF APPLICANT (City and State) G.D. Searle LLC 4901 Skokie Parkway Skokie, IL 60077.				4. AF NUMBER	
				5. SUPPLEMENT (S) NUMBER(S) DATES(S)	
6. NAME OF DRUG INSpra™		7. NONPROPRIETARY NAME Eplerenone Tablets		SE1-002	04-04-2003
8. SUPPLEMENT PROVIDES FOR: A new indication, for the treatment of heart failure.				9. AMENDMENTS DATES BC 08.22.2003	
10. PHARMACOLOGICAL CATEGORY Treatment of Heart Failure		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC		12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) Tablets		14. POTENCY 25 mg, 50 mg and 100 mg Tablets			
15. CHEMICAL NAME, STRUCTURE, MOLECULAR FORMULA AND MOLECULAR WEIGHT Pregn-4-ene-7,21-dicarboxylic acid, 9,11-epoxy-17-hydroxy-3-oxo, γ-lactone, methyl ester, (7α,11α,17α) $C_{24}H_{30}O_6$ 414.50 				16. RECORDS AND REPORTS CURRENT YES <input checked="" type="checkbox"/> NO REVIEWED YES <input checked="" type="checkbox"/> NO	
17. COMMENTS This supplement provides for a new indication. The applicant has cross-referenced the entire CMC information that was submitted in the original NDA. Since there is no change to the manufacturing process or to the manufacturing site(s) that was submitted in the original NDA and approved on September 27, 2002, an establishment inspection request was not submitted. There are no changes proposed to description, dosage and administration and how supplied section of labeling. A claim for categorical exclusion from filing an environmental assessment under 21 CFR 25.31 (a) has been submitted. The applicant's claim is found to be acceptable.					
18. CONCLUSIONS AND RECOMMENDATIONS Provided information is found to be adequate. This supplement is recommended for approval from the standpoint of chemistry, manufacturing and controls.					
19. REVIEWER					
NAME Nallaperumal Chidambaram, Ph.D.		SIGNATURE 			DATE COMPLETED 08-26-2003
DISTRIBUTION DNDC1/Division Dir. /DY. Director	ORIGINAL NDA	DIVISION FILE	Reviewer: N. Chidambaram Ph.D. HFD-110	CSO: D. Allis HFD-110	Chemistry Team Leader: K. Srinivasachar Ph.D. HFD-110

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Nallaperumal Chidambaram
8/26/03 02:20:52 PM
CHEMIST

Kasturi Srinivasachar
9/2/03 01:47:26 PM
CHEMIST